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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,464	10/29/2003	Mathai Mammen	P-142-US1	5983
27038	7590	03/20/2006	EXAMINER	
THERAVANCE, INC. 901 GATEWAY BOULEVARD SOUTH SAN FRANCISCO, CA 94080			PERLINGER, SARAH E	
			ART UNIT	PAPER NUMBER
			1625	
DATE MAILED: 03/20/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/696,464

Applicant(s)

MAMMEN ET AL.

Examiner

Sarah E. Perlinger

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-46 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-46 are pending.

2. ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-33, 39, 44-46 drawn to a compound of formula I wherein $p=1$ and one of W, X, Y, Z are nitrogen or $N \rightarrow O$, a pharmaceutical composition comprising a therapeutically effective amount of a compound of any one of claims 1-33 and a process for preparing a compound of formula I, classified in class 546 and various subclasses depending on a species election. If this group is elected, an election of species with regard to R^1 , R^2 , R^3 , W, X, Y, Z will also be required.
- II. Claims 1-17, 20-24, 39, 44-46 drawn to a compound of formula I wherein $p=1$ and two of W, X, Y, Z are nitrogen or $N \rightarrow O$, a pharmaceutical composition comprising a therapeutically effective amount of a compound of any one of claims 1-33 and a process for preparing a compound of formula I, classified in class 544 and various subclasses depending on a species election. If this group is elected, an election of species with regard to R^1 , R^2 , R^3 , W, X, Y, Z will also be required.
- III. Claims 1-19, 39, 44-46 drawn to a compound of formula I wherein $p=2$ and one of W, X, Y, Z are nitrogen or $N \rightarrow O$, a pharmaceutical composition comprising a therapeutically effective amount of a compound of any one of claims 1-33 and a process for preparing a compound of formula I, classified in class 546, subclasses 187-193 depending on a species election. If this group is elected, an election of species with regard to R^1 , R^2 , R^3 , W, X, Y, Z will also be required.
- IV. Claims 1-17, 39, 44-46 drawn to a compound of formula I wherein $p=2$ and two of W, X, Y, Z are nitrogen or $N \rightarrow O$, a pharmaceutical composition comprising a therapeutically effective amount of a compound of any one of claims 1-33 and a process for preparing a compound of formula I, classified in class 544 and various subclasses depending on a species election. If this group is elected, an election of species with regard to R^1 , R^2 , R^3 , W, X, Y, Z will also be required.
- V. Claim 34 drawn to a compound of formula IV, which is an intermediate of group II, classified in various classes and subclasses depending on a species election. If this group is elected, an election of species with regard to p, a, b, and c will also be required. Further restriction may be required.
- VI. Claim 35 drawn to a compound of formula V which is an intermediate of group II, classified in various classes and subclasses depending on a species election. If this group is elected, an election of species with regard to p, a, b, c-1 and G will also be required. Further restriction may be required.

- VII. Claim 36 drawn to a compound of formula VI which is an intermediate of group III, classified in various classes and subclasses depending on a species election. If this group is elected, an election of species with regard to p, d, b, and e will also be required. Further restriction may be required.
- VIII. Claim 37 drawn to a compound of formula VII which is an intermediate of group IV, classified in various classes and subclasses depending on a species election. If this group is elected, an election of species with regard to p, a, b, and c will also be required. Further restriction may be required.
- IX. Claim 38 drawn to a compound of formula VIII which is an intermediate of group V, classified in various classes and subclasses depending on a species election. If this group is elected, an election of species with regard to W, X, Y and z will also be required. Further restriction may be required.
- X. Claims 40-43 drawn to a method for treating a mammal having a medical condition alleviated by treatment with a muscarinic receptor antagonist, classified in various classes and subclasses. If this group is elected, an election of a particular medical condition and a species of the compound of claim 1 will also be required.

The inventions are distinct, each from the other because of the following reasons:

The compounds of groups I-IV differ in elements, bonding arrangements and chemical structure to such an extent that a reference anticipating any one group would not render another group obvious, thus unpatentability of any group would not necessarily imply unpatentability of another group. The search for each diverse core structure as delineated is not coextensive with each other and will constitute an enormous burden.

Inventions I-IV and V-IX are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product, and the species are patentably distinct (MPEP § 806.05(j)). In the instant case, the intermediate product is deemed to be useful as an intermediate to make another product (see GB 1575310, page 1, formula I and see page 3, intermediate formula V) and the inventions are deemed patentably distinct because there is nothing on this record to show them to be obvious variants.

Inventions I-IV and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method for treating a mammal having a medical condition alleviated by treatment with a muscarinic receptor antagonist can be practiced with another materially different product than the products of groups I-IX. For example, benzoxazines can be used in methods for treating a mammal having a medical condition alleviated by treatment with a muscarinic receptor antagonist (Bohme et

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al., *J. Med. Chem.*, 2002, 45, 4800, see compound 24 and Bohme et al., *J. Med. Chem.*, 2002, 45, 3094-3102, see conclusion and page 3101).

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Should applicant traverse on the ground that the groups are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the groups to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

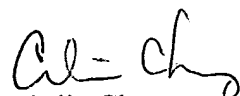
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Sarah E. Perlinger, whose telephone number is (571) 272-5574. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Cecilia Tsang, can be reached at (571) 272-0562. The fax number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SP

03/07/2006



Celia Chang
Primary Examiner
Art Unit 1625